

Food and Drug Administration Silver Spring MD 20993

EMPLOYEE/OFFICER LIST MEMO

To: The File
Date: May 16, 2016
BLA: STN 125597/0

Sponsor: PaxVax Bermuda Ltd.
Product: Cholera Vaccine, Live, Oral

From: Goutam Sen

Signature:

Section 916 of the Food and Drug Administration Amendments Act (FDAAA) requires that the identity of each employee or officer who participated in the decision to approve an original application be listed and filed as part of the Action Package for that file.

The following employees and officers have consented to have their names published publicly as being a participant in the approval decision for this file.

Richard Heath Coats

Oluchi Elekwachi

William McCormick, PhD

Deborah Trout

Facilities Reviewer

Labeling Reviewer

Division Director

Facilities Team Leader

Lisa Stockbridge, PhD

Jon Daugherty, PhD

Branch Chief
Branch Chief
Lihan Yan, PhD

Team Leader
Amelia Horne, PhD

Branch Chief

Goutam Sen, PhD Chair

Deepa Arya, MD, MPH, MBA Epidemiology Reviewer

Lokesh Bhattacharyya, PhD Chief

Alfred Del Grosso, PhD Product/CMC Reviewer

Christine Drabick, MS BiMo Reviewer

Kelsy Hoffman, PhD Regulatory Project Manager

Freyja Williams, BS

James Kenney, D.Sc.

Laboratory Chief
Tina Mongeau, MD

Clinical Reviewer
Scott Stibitz, PhD

Laboratory Chief

Manuel Osorio, PhD Serology Assay Reviewer Roshan Ramanathan, MD Clinical Team Leader

Christina Houck Regulatory Project Manager

Roger Plaut, PhD Product Reviewer
Scott Norris, BS Regulatory Coordinator
Jennifer Bridgewater, MPH Regulatory Coordinator